OIPE IAP76
APR 21 2008
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Appellant:	Favet et al.	Examiner:	Malamud, D.
Serial No.:	10/821,125	Group Art Unit:	3766
Filed:	April 8, 2004	Docket No.:	GUID.119PA
Title:	IMPLANTABLE SUDDEN CARDIAC DEATH PREVENTION DEVICE WITH REDUCED PROGRAMMABLE FEATURE SET		

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, April 17, 2007.

By: Rennae Johnson

AMENDED APPEAL BRIEF

Mail Stop Appeal Brief - Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amended Appeal Brief Section is submitted pursuant to 37 C.F.R. §41.37(d) for the above-referenced patent application in response to the Notification of Non-Compliant Appeal Brief dated March 18, 2008.

This amended appeal brief amends the title, and a complete amended appeal brief is submitted in accordance with MPEP §1205.03.

No fee is believed to be required for the filing of this Amended Appeal Brief; however, if it is determined that a fee is necessary, authority is given to charge/credit deposit account 50-3581 (GUID.119PA) in support of this filing.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee, Cardiac Pacemakers, Inc.

II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals, interferences or judicial proceedings that would have a bearing on the Board's decision in the instant appeal.

III. STATUS OF CLAIMS

Claims 1-68 remain pending. Each of the pending Claims 1-15 and 68 has been finally rejected by the Examiner's action dated March 23, 2007, from which Appellant appeals.

Claims 16-67 were withdrawn by the Examiner as being directed to non-elected inventions subject to a restriction requirement, which does not form part of this appeal.

Claim 68 was added in the Office action response filed January 25, 2007.

The pending Claims 1-15 and 68 under appeal may be found in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

No amendments have been presented subsequent to the final rejection dated March 23, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to minimally programmable implantable devices and methods for preventing sudden cardiac death. According to one embodiment, an implantable cardiac device includes a housing configured for implantation in a patient. Energy delivery circuitry is provided in the housing and configured to deliver only two forms of cardiac therapy. The two forms of cardiac therapy include a non-physiologic, life sustaining pacing therapy and a therapy to treat a tachyarrhythmia.

One embodiment of the present invention is directed to an implantable device for preventing sudden cardiac death. (*See, e.g.*, Claim 1, Page 20, Lines 11-18; Page 28, Line 24 – Page 29, Line 1; and Fig. 2, among other locations). Such embodiments can include a housing configured for implantation in a patient (*e.g.*, 301), energy delivery circuitry provided in the housing (*e.g.*, 300), the energy delivery circuitry configured to deliver only two forms of cardiac therapy, the two forms of cardiac therapy comprising a non-physiologic, life sustaining pacing therapy (*e.g.*, 330) and a therapy to treat a tachyarrhythmia (*e.g.*, 316), detection circuitry provided in the housing (*e.g.*, 302), the detection circuitry configured to detect cardiac rhythms, a lead system comprising one or more lead electrodes (*e.g.*, 314), the lead system coupled to the energy delivery circuitry and the detection circuitry, and control circuitry (*e.g.*, 305) provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of the tachyarrhythmia therapy in response to detection of a tachyarrhythmia requiring treatment and delivery of the non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole.

Such an embodiment may further include that the non-physiologic, life sustaining pacing therapy comprises delivery of pacing pulses at a rate between 5-20 pulses per minute (*See, e.g.*, Claim 68, Page 29, Line 12).

As required by 37 C.F.R. § 41.37(c)(1)(v), a concise explanation of the subject matter defined in each of the independent claims involved in the appeal is provided herein. Appellant notes that representative subject matter is identified for each of these claims; however, the abundance of supporting subject matter in the application prohibits identifying all textual and diagrammatic references to each claimed recitation. Appellant thus submits that other application subject matter, which supports the claims but is not specifically identified above, may be found elsewhere in the application. Appellant further notes that this summary does not

provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and their legal equivalents for a complete statement of the invention.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-12 stand rejected under 35 U.S.C. §102(b) over *Gill* (U.S. Patent No. 5,074,301).

B. Claims 13-15 and 68 stand rejected under 35 U.S.C. §103(a) over *Gill* (U.S. Patent No. 5,074,301).

VII. ARGUMENT

A. The rejection under 35 U.S.C. §102(b) of Claims 1-12 is improper because Gill fails to teach each of the claimed limitations.

Claims 1-12 each stand rejected under 35 U.S.C. §102(b) based upon U.S. Patent No. 5,074,301 to *Gill* (hereinafter "*Gill*"). In maintaining the rejection, the Examiner appears to take the untenable position that any pacing therapy, including *Gill's* bradycardia therapy, constitutes a non-physiologic, life sustaining pacing therapy.

Appellant's independent Claim 1 recites, among other features, control circuitry provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of the tachyarrhythmia therapy in response to detection of a tachyarrhythmia requiring treatment and delivery of the non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole.

Gill discloses an implantable medical device to detect ventricular tachycardia and ventricular fibrillation and "deliver therapy in the form of electrical energy to cardiac tissue to revert tachycardia and restore sinus rhythm." (Col. 1, Lines 8-12). *Gill* acknowledges that the heart may be stopped after delivery of cardioversion therapy. (Col. 6, Lines 34-37; Fig. 4C). Therefore, *Gill's* device delivers bradycardia pacing therapy after the delivery of cardioversion therapy and detection of asystole as part of *Gill's* therapy regime to restore sinus rhythm. (Col. 6, Lines 34-39; Fig. 4C). Appellant respectfully submits that *Gill's* teaching of delivering bradycardia pacing to treat asystole and restore sinus rhythm does not constitute an anticipatory teaching of a non-physiologic, life sustaining pacing therapy.

Bradycardia pacing therapy, as understood by one having ordinary skill in the art, paces a heart faster than the current intrinsic rate to increase cardiac output and support physiologic function of a patient. For example, although *Gill* does not explicitly define bradycardia pacing, *Gill* does discuss "a bradycardia support system as well as a high energy shock system to revert ventricular tachycardia to normal sinus rhythm." (Col. 1, Line 68 – Col. 2, Line 2; emphasis added). *Gill's* invention delivers a high energy shock followed by bradycardia pacing to restore sinus rhythm. (Col. 1, Lines 9-12; Fig. 4C).

As quoted in MPEP § 2131, "the identical invention must be shown in as complete detail as is contained in the ... claim." (*Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9

USPQ2d 1913, 1920 (Fed. Cir. 1989)). Appellant respectfully submits that *Gill* does not disclose delivery of a non-physiologic, life sustaining pacing therapy, as recited in independent Claim 1. Nothing from *Gill's* disclosure teaches that *Gill's* bradycardia pacing is anything but conventional bradycardia pacing that supports cardiac output to restore physiologic function due to restoration of normal sinus rhythm. (Col. 1, Lines 9-12; Col. 1, Line 68 – Col. 2, Line 2; and Fig. 4C).

Furthermore, not only does *Gill* fail to disclose a non-physiologic, life sustaining pacing therapy, but *Gill's* disclosure of a bradycardia therapy diverges from a teaching of a non-physiologic, life sustaining pacing therapy, such that the two therapies would be understood to be materially different by one having ordinary skill in the art.

For example, the differences between non-physiologic, life sustaining pacing therapy and bradycardia pacing therapy are highlighted by the Specification as follows:

> An implantable cardiac device of the present invention finds particular utility in the context of preventing sudden cardiac death (SCD) in patients that may not require a traditional implantable cardiac defibrillator (ICD). Although ICDs are very effective at preventing SCD, most people at risk of SCD are not provided with implantable defibrillators. Many people that are at risk of SCD, for example, may not have a history of arrhythmias or other comorbidities that are often considered threshold factors that must be present before a person can receive an ICD. The high costs of conventional ICDs (device and surgical implant costs), and the relatively stringent requirements that a candidate patient must satisfy in order to justify the risks and costs of conventional ICD implantation, may also significantly limit the number of patients that can receive a conventional ICD. Other reasons why people at risk of SCD do not receive conventional ICDs, particularly those that have a cardiac pacing capability, include the limited number of physicians qualified to perform lead/electrode implantation and pacing threshold determinations, and a limited number of surgical facilities adequately equipped to accommodate such cardiac device implant procedures. Each year, SCD claims the lives of some 300,000 Americans—with 80% to 90% of those deaths caused by ventricular fibrillation.

It is believed that an implantable cardiac device of the present invention may be appropriate for implantation in a significantly larger patient population than that for which conventional ICDs are appropriate. [Page 7, Line 10 – Page 8, Line 3]

. . .

Embodiments of the present invention are directed to maintaining circulatory support by providing post-shock pacing pulses from an SCDP device. Embodiments of the present invention are directed to post-shock asystole prevention using post-shock pacing therapies. According to one approach, and in contrast to conventional bradycardia pacing modalities, normal heart rate is not maintained by the SCDP device. Rather, a single pacing pulse is delivered after a predetermined interval following detection of the last R-wave or delivery of a pace pulse (i.e., asystole detection). Delivery of post-shock pacing pulses is terminated once the heart is able to beat on its. [Page 28, Lines 15-23; emphasis added]

Furthermore, Appellant's Specification identifies a "non-physiologic, life sustaining pacing therapy" as pacing at a rate lower than bradycardia pacing. ("[i]n an embodiment in which asystole prevention pacing is also made available, the SCDP device 502 produces pacing pulses in accordance with a non-physiologic, life sustaining pacing therapy, such as pacing therapy deliverable at a rate lower than a bradycardia pacing rate." Specification, Page 20, Lines 15-18).

Appellant respectfully submits that the above passages of the Specification highlight that bradycardia therapy and a non-physiologic, life sustaining pacing therapy are materially different therapies with different goals and different parameters to accomplish their respective goals.

Appellant is well aware that limitations from the Specification are not read into the Claims, as remarked in the Office Action of March 28, 2007. However, Appellant notes that reference to the Specification to understand claim terms is well known as an acceptable means to highlight difference between the claims and prior art. (See *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)).

Moreover, to any extent that the Appellant's claimed reference to a non-physiologic, life sustaining pacing therapy is not clear, the Appellant notes Appellants are their own

lexicographers and can define claim terms, including those with special meanings, in the Specification. (MPEP § 2173.01). In contrast to *Gill's* bradycardia therapy that paces until normal sinus rhythm is restored (Col. 1, Lines 9-12; Col. 1, Line 68 – Col. 2, Line 2; and Fig. 4C), Appellant's non-physiologic, life sustaining pacing therapy is identified in the Specification as a pacing therapy with a rate lower than bradycardia pacing and terminated once the heart is able to beat on its own (Page 20, Lines 15-18 and Page 28, Lines 15-23).

Moreover, even without reference to the Specification, considering that *Gill's* bradycardia therapy restores sinus rhythm, as discussed above, one having ordinary skill in the art would readily recognize that such a bradycardia therapy is materially different than the Appellant's non-physiologic, life sustaining pacing therapy.

Claims 2-12 that depend from independent Claim 1 are also not anticipated by *Gill*. These dependent claims include all of the limitations of independent Claim 1 and recite additional features which further distinguish these Claims from *Gill*. Therefore, dependent Claims 2-12 are not anticipated by *Gill* for at least the same reasons that independent Claim 1 is not anticipated by *Gill*, as discussed above.

For each of the reasons discussed above, Appellant respectfully submits that claims 1-12 recite features that are not taught by *Gill's* disclosure. Consequently there is an omission of at least one essential element required for a proper anticipation rejection of independent Claim 1 and its associated dependent Claims 2-12, and the anticipation rejection of these Claims should be reversed at least on that basis.

B. The rejection under 35 U.S.C. §103(a) of Claims 13-15 and 68 is improper because Gill fails to teach or suggest each of the claimed limitations.

Appellant maintains the traversal of the rejection of dependent Claims 13-15 and 68 because each of these Claims depends from independent Claim 1. Appellant respectfully submits that *Gill* fails to teach or suggest each element and limitation of independent Claim 1, for the reasons discussed above. Dependent Claims 13-15 and 68 that depend from independent Claim 1 are also not rendered obvious by *Gill*. These dependent Claims include all of the limitations of independent Claim 1 and recite additional features which further distinguish these Claims from *Gill*. Therefore, dependent Claims 13-15 and 68 are not rendered obvious by *Gill* for at least the same reasons that independent Claim 1 is not rendered

obvious by *Gill*, and the §103(a) rejection of these claims should be reversed at least on that basis.

1. Dependent claim 68

In specific regard to dependent Claim 68, Appellant respectfully submits that *Gill* does not teach or suggest that the non-physiologic, life sustaining pacing therapy of independent Claim 1 comprises delivery of pacing pulses at a rate between 5-20 pulses per minute, as recited in dependent Claim 68.

In addressing this dependent Claim, the Examiner states that it "would have been obvious to one having ordinary skill in the art at the time the invention was made to deliver pacing pulses at a rate of 5-20 pulses per minute, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233." (Page 4 of the Office Action mailed March 28, 2007). However, Appellant respectfully submits that range of Claim 68 for non-physiologic, life sustaining pacing therapy is not an obvious optimized range in light of *Gill*. Rather, as discussed above, *Gill* and the claimed non-physiologic, life sustaining pacing therapy have different therapeutic goals, and go about delivering therapy in divergent ways.

"A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. (MPEP § 2144.05(II)(b); discussing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (the claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable)).

Appellant respectfully submits that the non-physiologic, life sustaining pacing therapy pulses delivered at a rate between 5-20 pulses per minute is not an obvious optimization of *Gill*, but is instead a therapy with different goals and different parameters to effect these goals.

Gill does not disclose a non-physiologic, life sustaining pacing therapy as discussed above, and therefore does not disclose such a therapy with a pacing rate between 5-20 pulses per minute, as recited in dependent Claim 68.

Accordingly, the §103(a) rejection of dependent Claim 68 is unsupported and unwarranted, and should be reversed for at least this reason.

VIII. CONCLUSION

In view of the above, Appellant respectfully submits that the claimed invention is patentable over the cited reference and that the rejection of Claims 1-15 and 68 should be reversed. Appellant respectfully requests reversal of the rejection as applied to the appealed Claims and allowance of the entire application.

Authorization to charge the undersigned's deposit account is provided on the cover page of this brief.

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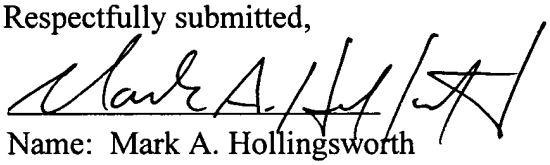
Respectfully submitted,



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CLAIMS APPENDIX

1. An implantable device for preventing sudden cardiac death, comprising:

a housing configured for implantation in a patient;

energy delivery circuitry provided in the housing, the energy delivery circuitry configured to deliver only two forms of cardiac therapy, the two forms of cardiac therapy comprising a non-physiologic, life sustaining pacing therapy and a therapy to treat a tachyarrhythmia;

detection circuitry provided in the housing, the detection circuitry configured to detect cardiac rhythms;

a lead system comprising one or more lead electrodes, the lead system coupled to the energy delivery circuitry and the detection circuitry; and

control circuitry provided in the housing and coupled to the energy delivery circuitry and the detection circuitry, the control circuitry configured to coordinate delivery of the tachyarrhythmia therapy in response to detection of a tachyarrhythmia requiring treatment and delivery of the non-physiologic, life sustaining pacing therapy in response to detection of cardiac asystole.

2. The device of claim 1, wherein the tachyarrhythmia therapy comprises a single therapy to treat cardiac fibrillation.

3. The device of claim 1, wherein the pacing therapy comprises a single pacing therapy to treat the cardiac asystole.

4. The device of claim 1, wherein the tachyarrhythmia therapy comprises a single therapy to treat cardiac fibrillation, and the pacing therapy comprises a single pacing therapy to treat the cardiac asystole.

5. The device of claim 1, wherein the pacing therapy comprises a single pacing therapy to treat the cardiac asystole, and the tachyarrhythmia therapy comprises a first therapy to treat cardiac fibrillation and a second therapy to treat a tachycardia.

6. The device of claim 1, wherein the tachyarrhythmia therapy comprises a therapy to treat a tachycardia.

7. The device of claim 1, wherein the tachyarrhythmia therapy comprises an anti-tachycardia pacing therapy.

8. The device of claim 1, wherein the tachyarrhythmia therapy comprises a therapy to treat cardiac fibrillation.

9. The device of claim 1, wherein the tachyarrhythmia therapy comprises a monophasic defibrillation therapy.

10. The device of claim 1, wherein the tachyarrhythmia therapy comprises a biphasic defibrillation therapy.

11. The device of claim 1, wherein the tachyarrhythmia therapy comprises a therapy to treat tachycardia and a therapy to treat cardiac fibrillation.

12. The device of claim 1, wherein the energy delivery circuitry comprises a capacitor circuit and the tachyarrhythmia therapy comprises a defibrillation therapy and a cardioversion therapy, the cardioversion therapy delivered prior to or during charging of a capacitor of the capacitor circuit.

13. The device of claim 1, wherein at least some of the lead electrodes are configured for intrathoracic placement.

14. The device of claim 1, wherein one or more of the lead electrodes are configured for subcutaneous non-intrathoracic placement.

15. The device of claim 1, wherein the housing comprises a housing electrode.

16-67. (Withdrawn)

68. The implantable device of claim 1, wherein the non-physiologic, life sustaining pacing therapy comprises delivery of pacing pulses at a rate between 5-20 pulses per minute.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.